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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,524	07/18/2003	Raymond A. Hui	RDId 01072CIP US	4118

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EXAMINER	
CEPERLEY, MARY	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,524	HUI ET AL.	
	Examiner	Art Unit	
	Mary (Molly) E. Ceperley	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-38 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-38 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/8/2004.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1) Reference AT of form PTO-1449 filed April 08, 2004 has been considered but will not be published on the front of any patent issuing from this application for the reason that the citation does not contain a publication date as required by 37 CFR 1.98(b)(5).

2) Citations AW and AX of form PTO-1449 filed April 08, 2004, each of which contains citations of *multiple* publications, have not been considered since they fail to provide the information required by 37 CFR 1.98(b)(5) for *each* publication cited; applicants have further failed to provide a copy of *each* publication cited as required by 37 CFR 1.98(a)(2)(a). Applicants are reminded of their duty to disclose information material to patentability in accordance with 37 CFR 1.56, particularly subparagraph (a)(2), namely:

> "The *closest* information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, *to make sure that any material information contained therein is disclosed to the Office*."

Applicants are advised that the citation of a large number of documents, without a discussion of the relevance of each document to the claimed invention, increases the risk that documents of particular relevance will not be adequately considered by the examiner during prosecution.

3) Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

4) The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5) Claims 9, 12, 15, 33 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claims 33 and 36 are indefinite in not reciting the type/structure of the "analyte" to be detected. Additionally, claims 33 and 36 are indefinite and incomplete for the reason that they fail to define how the "complex" formed by the antibody and the analyte" is to be detected; presumably the use of a tracer or labeled secondary antibody would be required to practice the methods.

b) Claims 12 and 15 are rejected as being indefinite in the use of the term "in a manner equivalent to". It is not clear what is meant by this term and the exact scope of the claim cannot be determined.

c) The claim 9 definition of "Q" is "a macromolecular carrier" while the definition of "Q" in claim 7, from which claim 9 depends, is "a leaving group".

6) A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7) Claims 1-9, 16 and 22-38 of this application conflict with claims 1-45 of Application No. 10/087,612. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

8) Claims 1-6, 29 and 30 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-4, 7, 31 and 36 of copending Application No. 10/087,612. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

9) The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10) Claims 11, 12, 14-28 and 33-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17, 18, 31 and 42-44 of copending Application No. 10/087,469. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed antibodies of both applications have the same specificity, i.e. specificity for an ecstasy drug, in particular, specificity for MDEA.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11) Claims 11, 12 and 14-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8 and 9 of copending Application No. 10/622,254. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed antibodies of both applications have the same specificity, i.e. specificity for MDEA.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13) Claims 1-4, 6, (activated haptens, tracers and immunogens) 11, 12, 14-25 (antibodies), 26-28 (antibody-containing kits), 29, 32 (production of antibodies) and 33-38 (immunoasays) are rejected under 35 U.S.C. 102(b) as being anticipated by each of Gross (US 3,996,344), Soares (US 4,016,146), Buechler et al (US 5,470,977), Huber et al (US 5,976,812), Heiman et al (US 5,262,333), Hu et al (US 5,135,863), Byrnes et al (US 4,868,132) or Schneider et al (US 3,878,187).

Each of the references describes methamphetamine derivatives in which the phenyl ring is substituted at the *para* position with an activated linker moiety. The linker moiety can be reacted with an immunogenic carrier or label to form the corresponding *para*-substituted methamphetamine immunogen (useful for developing antibodies) or detectably labeled methamphetamine derivative (tracer). The *para*-substituted activated haptens, immunogens, tracers and antibodies of the references anticipate the *para*-substituted activated haptens, immunogens, tracers and antibodies of the instant claims. Given the structural similarities of the haptens of the instant invention and those of the prior art, the antibodies of the prior art would be expected to inherently have the same specificity for MDEA as the antibodies of the instant claims. See:

i) Gross: col. 3, line 10 – col. 4, line 5; col. 6, formula (5); col. 7, lines 47-48; Examples 1c. and 1d.; Example 2; claims 1, 5, 6 and 9;

ii) Soares: formula (5); col. 15, lines 9-13; claim 1;

iii) Buechler et al: Fig. 1, Example 15 ; col. 2, lines 40-42 ; col. 6, line 1 – col. 8, line 31; Examples 2, 4-8 and 10;

iv) Huber et al: Fig. 2, structures 15 – 17 ; col. 2, line 40 ; col. 3, line 50; claims 1-22;

v) Heiman et al: Structures 7, 8, 12 and 13 ; col. 21, lines 13-26;

vi) Hu et al: claim 1; col. 32, 9. ;

vii) Byrnes et al : FIGS. 2-B, 7, 9-A and 9-D ;

viii) Schneider et al : EXAMPLES II and III ; col. 12, lines 18-26.

14) Claims 5, 7-9, 30 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Huber et al (US 5,976,812).

Huber et al describes *para*-derivatized amphetamine haptens wherein the linker contains both an alkylene moiety directly attached to the benzene ring and a carbonyl group; these activated haptens are useful in preparing the corresponding amphetamine immunogens, antibodies and tracers and anticipate the corresponding immunogens, tracers, antibodies and their method of use in an immunoassay of instant claims 5-7 wherein "L" is alkylene and "X" is "-CO-". See Huber et al: structures 13, 14, and 16 – 18. Claims 7-9 and 31 contain the added limitation that "R^{1}" is ethyl and "R^{2}" is methyl, i.e. the terminal amine group is -N(Et)Me . Huber et al specifically describe this compound limitation at col. 2, lines 32-47 wherein "R_4" and "R_5" can be $-CH_3$ (methyl) or $-C_2H_5$ (ethyl), i.e. the terminal amine group is –N(Et)Me. Therefore Huber et al anticipates the instant claims.

15) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 02, 2004

Mary (Molly) E. Ceperley
Primary Examiner
Art Unit 1641